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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                  | CONFIRMATION NO.       |
|---|-------------|----------------------|--------------------------------------|------------------------|
| 10/822,663  | 04/13/2004  | Katsuaki Takahashi   | KAS-204                              | 3101                   |
| 24956 7590 06/19/2007<br>MATTINGLY, STANGER, MALUR & BRUNDIDGE, P.C.<br>1800 DIAGONAL ROAD<br>SUITE 370<br>ALEXANDRIA, VA 22314 |             |                      | EXAMINER<br>WRIGHT, PATRICIA KATHRYN |                        |
|   |             |                      | ART UNIT<br>1743                     | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>06/19/2007              | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                   |                  |  |
|------------------------------|-------------------|------------------|--|
| <b>Office Action Summary</b> | Application No.   | Applicant(s)     |  |
|                              | 10/822,663        | TAKAHASHI ET AL. |  |
|                              | Examiner          | Art Unit         |  |
|                              | P. Kathryn Wright | 1743             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/2004; 4/2004</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-5, in the reply filed on May 15, 2007 is acknowledged.
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

4. The information disclosure statement filed August 06, 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language (i.e. JP 6-64070). It has been placed in the application file, but the information referred to therein has not been considered.

### ***Drawings***

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "sample container transfer mechanism" and the "measuring mechanism" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The specification states at page 4, third paragraph, that "[s]amplers for an automatic analyzer... are broadly divided into a disk sampler type and a rack sampler type". It is presumed by the Examiner that this is referring to the "sample container transfer mechanism". However, the sample transfer mechanism does not correspond with any reference number in the figures. Thus, Applicant should amend the specification so that the "sample container transfer mechanism" is clearly correlated to one or more elements in the figures (i.e., sample disk 1) without introducing new matter.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 11 (Fig. 1), 16 (Fig. 2). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by

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the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "sample container transfer mechanism" and "measuring mechanism" in claim 1.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the "sample container transfer mechanism"; however it is not clear to the Examiner whether this mechanism corresponds to the disclosed "sampler" and "mechanism for transferring a sample container...broadly divided into a disk sampler type and a rack sampler type", see page 4, third full paragraph. For the purposes of examination this limitation will be interpreted as a disk type or rack type container holder. However clarification is required.

Furthermore, claim 1 recites the “sample dispensing mechanism for dispensing a sample in the sample container”. This is confusing and indefinite since the figures and specification disclose the sample dispensing mechanism 3 for dispensing a sample from the sample container into a reaction vessel. Clarification is requested.

Claim 1, line 6 recites the limitation “the sample dispensing position”. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 is also confusing because applicant has mixed the two classes of invention (apparatus and method) into one independent claim. Since two separate statutory type claims are combined into a single claim, it is not clear as to which type of claim is being presented. Applicant appears to be claiming an apparatus since the preamble recites an automatic analyzer. Thus, for the purpose of the examination the process steps or functional language following the “wherein the automatic analyzer further comprises the mechanisms of...” cannot be relied upon to distinguish over the prior art.

Similarly, claims 2-4, recite processes or functional language describing the use of the analyzer. Only structural language is determinative of the metes and bounds of an apparatus claim. An apparatus claim covers what a device is, not what it does. Functional recitations, standing alone, while perhaps helpful in understanding the meaning of a claim and the invention that it represents, cannot be relied upon to distinguish over the prior art. Nevertheless, functional language in the claims must be given full weight and may not be disregarded in evaluating the patentability of the subject matter defined employing such functional language. However, Applicant must

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establish through convincing evidence that what is expressly taught by the prior art does not inherently function in the manner required by the claim.

Claim 5 recites "a sample container". It is not clear whether this the same or a different sample container than the one referred to in claim 1. Furthermore, the functional language following the recitation of the "cover" in claim 5 cannot be relied upon to distinguish over the prior art for the reasons discussed above.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent no. 5,827,479 to Yamazaki et al., hereinafter "Yamazaki".

Yamazaki teaches an automatic analyzer system as currently claimed. Yamazaki teaches a container 33 for holding a liquid and liquid dispensing mechanisms 5a,5b for dispensing liquid into the container. The container includes an information recording medium 20, 21 on which information for identifying the liquid in the container is recorded (i.e., bar code, IC chip). The information reading medium is attached to the container. Furthermore, the analyzer system of Yamazaki includes a container transfer mechanism (i.e., carousel 4, 4a, 4b) for transferring the containers to the dispensing position in the dispensing mechanism (Figs. 1).

With respect to claim 4, Yamazaki teaches the container transfer mechanism is a rotating carousel wherein the containers are mounted along the circumference thereof to the dispensing position (col. 4, lines 46+).

Furthermore, Yamazaki teaches a cover 11 capable of preventing the container from being taken out of the transfer mechanism until the dispensing mechanism dispenses the liquid from the container.

The system of Yamazaki also includes a reaction vessel 30 where the liquid dispensed by the dispensing mechanism is discharged and mixed with a sample and a measuring mechanism 12 for measuring a reaction within the reaction vessel (see Fig. 1).

With respect to claim 3, Yamazaki teaches an alarm means that displayed on the operating unit when the amount of fluid is "different than before" i.e., depleted.

Please note that while the fluid containers of Yamazaki are used to dispense reagent rather than sample as claimed, a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

As discussed above, the method or process of using the above described analyzer is not determinative of the metes and bounds of an apparatus claim. While the prior art is not used to perform the specific process steps disclosed in the claims, such limitations are merely an intended use which the prior art would inherently be capable of



doing. It appears the only distinction between applicant's claims and the prior art is recited functional language. Thus, it is incumbent upon Applicant to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re Ludtke*, 169 USQ 563 (CCPA 1971).

12. Claims 1-3, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent no. 5,314,825 to Weyrauch et al., hereinafter "Weyrauch".

Weyrauch teaches an automatic analyzer system 24 substantially as claimed. Weyrauch teaches a sample container 27 for holding a sample and a sample dispensing mechanism 18 for dispensing sample into the sample container. The sample tube includes an information recording medium on which information for identifying a sample in the sample container is recorded (i.e., bar code). The information reading medium is attached to the sample container. Furthermore, the analyzer system of Weyrauch includes a sample container transfer mechanism 140 for transferring the sample container to the sample dispensing position in the sample dispensing mechanism (Figs. 37-46). Furthermore, Weyrauch teaches a cover 180 for preventing a sample container from being taken out of the sample transfer mechanism until the sample dispensing mechanism dispenses the sample from the container.

The system of Weyrauch also includes a reaction vessel 10 wherein the sample dispensed by the sample dispensing mechanism is discharged and mixed with a reagent and a measuring mechanism 215 for measuring a reaction in the reaction vessel (see Fig. 31).

As discussed previously, the method or process of using the above described analyzer is not determinative of the metes and bounds of an apparatus claim. While the prior art is not used to perform the specific process steps disclosed in the wherein clauses of the claims, such limitations are merely an intended use which the prior art would inherently be capable of doing. Thus, it is incumbent upon Applicant to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re Ludtke*, 169 USOQ 563 (CCPA 1971).

### ***Conclusion***

13. No claims allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: Kanamori et al., Sakazume et al., and Gilford are cited for teaching automatic analyzers capable of utilizing information recorded on fluid containers for identification and analysis.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 13, 2007

pkw

  
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